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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/830,400

07/20/2001

Lee M. Nadler

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7028

7590

10/30/2006

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EXAMINER

JUEDES, AMY E

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/830,400	Applicant(s) NADLER ET AL.	
	Examiner Amy E. Juedes, Ph.D.	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 20-43, 45 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1644

#### DETAILED ACTION

1. Applicant's election of group VI, claims 18-19 and 44, in the reply filed on 8/21/06 is acknowledged. Applicant has also elected SEQ ID NO: 1 as the species of hTERT peptide. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-17, 20-43, and 45-46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 18-19 and 44 read on the elected invention and are being acted upon.

2. Applicant's information disclosures, filed 8/2/01, 5/17/01, and 2/11/03, are acknowledged. However, cite B3 from the 2/11/03 IDS, and Schultze et al. and Vonderheider et al. from the 8/2/01 IDS have been lined through, since the references could not be located in the file. Additionally, the Schultze et al. reference has not been identified by date of publication, as is required. Likewise, the B3 citation requires a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, since it appears not to be in the English language. Additionally, the search report citation has been lined through, since all of the references cited on the report are already listed on the information disclosure statements, and note that the search report itself is not listed in the required format.

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-19 and 44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed peptides, as written, read on naturally processed tumor peptides that are present in a human being. A human being is not-statutory subject matter. See 1077 O.G. 24, April 21, 1987.

Art Unit: 1644

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-19 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of "hTERT peptides" or "universal tumor-associated antigens or peptides thereof" that bind to a major histocompatibility complex.

The recitation of "hTERT peptides" that bind to a major histocompatibility complex is the recitation of a broad range of structurally different peptides with unique amino acid sequences. For example, the claims might encompass virtually any fragment of hTERT. Additionally, in the absence of a specific definition of the term hTERT, the claims might even encompass mutated peptides derived from hTERT. Furthermore, the claims encompass peptides that function bind to any major histocompatibility complex class I or class II allele from any species (for example A, B, C, DQ, DR, etc. from human or H2-b, H2-d, IA, IE etc. from mouse). Said peptides would all be structurally different, since the interaction with a particular MHC allele is mediated by the specific amino acid sequence of a peptide. While Applicant has disclosed several closely related species of hTERT peptide, they all bind to the human MHC class I A allele. The disclosure of said related peptides is not sufficient to represent the broad genus of claimed hTERT peptides that bind to any MHC class I or II allele from any species.

Additionally, the recitation of "universal tumor associated antigens" represents a broad range of different proteins. The specification on page 6 defines a tumor antigen as "universal" if it is expressed in tumors of different origins. Based on this definition, the instant claims might encompass virtually any

Art Unit: 1644

tumor antigen (for example those that are expressed in tumors isolated from different patients, different organs, etc.). Thus, the claims encompass a broad range of structurally different tumor antigens. Additionally, the claims encompass functionally different antigens, for example some tumor antigens are growth or differentiation factors, while others function as cell adhesion molecules. Furthermore, the claims encompass peptides derived from any tumor antigen that bind to any major histocompatibility complex. As described above, this represents a broad range of structurally different peptides. Furthermore, Applicant has only disclosed hTERT and hTERT peptides. This cannot be considered adequate to represent the broad range of structurally different proteins encompassed by the claims. Thus, one of skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-19 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No: 6,475,789.

The '789 patent teaches hTERT peptides (see SEQ ID NO: 319, in particular). Furthermore, SEQ ID NO: 319 comprises peptides that binds to a major histocompatibility complex molecule, including a peptide "consisting essentially" of SEQ ID NO: 1 of the instant application (see residues 495-503 of SEQ ID NO: 319).

Thus, the reference clearly anticipates the invention.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy

Art Unit: 1644

reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claim 44 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 4 of copending Application No. 11/137,253. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 4 of the '253 application is drawn to isolated epitopes of various tumor antigens, including telomerase, MAGE, etc. (i.e. universal tumor antigens), and thus represent species of the more generic universal tumor antigen now claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claim 44 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being

Art Unit: 1644

unpatentable over claim 26 of copending Application No. 10/130,413. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 26 of the '413 application is drawn to a cytochrome P450 1B1 peptide that binds to a major histocompatibility complex (i.e. a universal tumor antigen), and thus represents a species of the more generic universal tumor antigen now claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

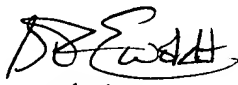
9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 21, 2006

  
10/2/06  
G.R. EWOLDT, PH.D.  
PRIMARY EXAMINER